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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,412	04/01/2008	Carlos Manuel Miyares Cao	LEX P37	5240
28752 7590 11/23/2010 LACKENBACH SIEGEL, LLP LACKENBACH SIEGEL BUILDING 1 CHASE ROAD SCARSDALE, NY 10583				
EXAMINER				
VAKILI, ZOHREH				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,412

Applicant(s)

MIYARES CAO ET AL.

Examiner

ZOHREH VAKILI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/22)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 6-11 are presented for examination.

Applicant's Amendment filed July 8, 2010 has been received and entered into the present application. Claims 6-11 are pending and are herein examined on the merits.

Applicant's arguments, filed July 8, 2010 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claim is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as

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the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 1 12, first paragraph with respect to the claimed invention." (MPEP 2173).

The term "70-90 degrees" is not clear what Applicant is referring to, which renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Because the term "70-90 degrees" would invite subjective interpretations of whether or not this temperature is measured in Celsius or Fahrenheit, if this temperature is considered for the whole composition, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims fail to meet either the tenor or express requirements of 35 U.S.C. 1 12, second paragraph and are properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costanzo (US Pat. No. 6323219 B1).

This invention relates to methods and compositions for bringing about changes in skin pigmentation and for treating inflammatory disorders. More particularly, this invention relates to compounds which affect melanogenesis and can be used as depigmenting agents or as agents for darkening skin utilizing the PAR-2 pathway (see abstract). Costanzo further teaches the composition of **compound I in 70% ethanol** as solvent 1 with a range of 40-90% (see col. 26, example 19). Skin disorders include unwanted pigmentation, unwanted depigmentation. In one specific example, vitiligo patients are treated with melanin (col. 30, lines 15-18). In the compounds of formula (I): The particularly preferred "A"s are: amino, an **L amino** acid such as glycine or **proline**, where

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the amino terminus is unsubstituted or monosubstituted with a member of the group consisting of **amino, or a poly peptide comprised of two amino acids, where the first acid is L-proline** (col. 35, lines 57-66 and col. 36, lines 5-9).

Skin disorders include unwanted pigmentation, unwanted depigmentation. In one specific example, **vitaligo** patients are treated with melanin (col. 30, lines 15-18). Claim 2 indicates the alcoholic excipient is 0.52 mg/ml of the composition. Costanzo teaches the composition in ethanol as a solvent with a range of 40-90%, where it indicates that 50% of the composition consists of the solvent which reads on 0.52 mg/ml being the solvent, therefore the teachings of Costanzo reads on claim 8.

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. PPG Industries Inc. V Guardian Industries Corp. 48 USPQ2d 1351 (Fed. Cir. 1998) and In re De Lajarte 337 F.2d 870, 143 USPQ 256 (CCPA 1964) See MPEP 2111.03.

It would have been obvious to have used the teachings of Costanzo to produce a composition for the treatment of vitiligo.

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One would have been motivated to create such formulation because Costanzo teaches the preparation of a compound containing amino acid such as L-proline in an alcoholic vehicle such as ethanol. Therefore, one of ordinary skill in the art would have been motivated to use the formulation taught by Costanzo to develop the claimed formulation. It will be apparent to one of ordinary skill in the art that many changes and modifications can be made thereto without departing from the spirit or scope of the appended claims. The determination of the alcoholic excipient to the active ingredient are well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug while minimizing adverse or unwanted side effects or even undesirable stability issues.

Finally, one would have a reasonable expectation of success given that Costanzo provide a detailed blueprint for making the composition for the treatment of vitiligo, and the steps of which are routine to one of ordinary skill in the art.

Thus in the absence of evidence to the contrary, the invention of claims 1-4 would have been prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Claim Objection

Claims 10 and 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims.

Response to Arguments and Remarks

Applicant argues the "degree" symbol is understood in some countries in Europe and Latin America as an alcohol concentration unit of measure and sometimes expressed as "degrees Gay-Lussac".

Applicant's arguments are not persuasive the degree symbol is not commonly used here USA and not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant's arguments in regard with formula I of the prior art reference is not persuasive; the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App.

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1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). The art explicitly teaches Skin disorders include unwanted pigmentation, unwanted depigmentation. Further, the stimulation of melanin as claimed in the instant claim composition is an intended use. An intended use in a composition claim and does not have a patentable weight. An intended use fails materially or physically limit the structure of the composition of the prior art can perform such a use, then it meets the claims. Applicant's remarks have been fully and carefully considered in their entirety, but fail to be persuasive.

Applicant's amendments and remarks have been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

Conclusion

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory

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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner 1614

November 15, 2010

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/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614